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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,500	01/20/2000	Klaus M. Irion	02581-P0204A	4514

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Wesley W Whitmyer Jr
St Onge Steward Johnston & Reens LLC
986 Bedford Street
Stamford, CT 06905-5619

EXAMINER

POTHIER, DENISE M

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/488,500

Applicant(s)

IRION, KLAUS M.

Examiner

Denise M Pothier

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-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Summary

1. On August 29, 2002, Applicant filed a request for reconsideration with regards to claims 1-44.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on July 24, 1997. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

3. The German references DE 195 29 950 and DE 39 33 159 have been considered. However since Applicant has stated on page 12 that DE 197 31 894 is not prior art, this reference has been placed in the file but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 3-14,¹⁹23 and 25-36⁴¹ are rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli in view of Gain. See paragraph 10 of the previous office action. In addition to elaborate, Gain teaches in column 2, lines 59-68 and column 3,

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line 1-6 different materials that can be selected as the photoluminescent material, such as eosine, fluorescein, and rhodamine. Rhodamine is an example of a material that autofluoresces and fluoresces in the range of a tumor-specific photosensitizer using part of the visible white light spectrum. Thus, the marking discloses in Iacovelli and the materials taught by Gain can be excited to fluoresce by a light source as recited in claims 1 and 23 in order to improve visibility and delineate devices during surgery. In addition, Iacovelli discloses and Gain teaches that the fluorescing substance is selected in such a way that its excitation range lies in the excitation range of a tumor-specific photosensitizer or in the excitation range of a tissue-autofluorescence (using a Rhodamine material).

6. Claims 2 and ²⁴4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli in view of Gain as applied to claims 1 and 23 above, and further in view of Richards-Kortum. See paragraph 11 of the previous office action.

7. Claims 12-13 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli in view of Gain as applied to claims 1 and 23 above, and further in view of Sugai. See paragraph 12 of the previous office action.

8. Claims 15-18, 20-22, 37-39 and ⁴⁰42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli in view of Gain as applied to claims 1 and 23 above, and further in view of Nakamura. See paragraph 13 of the previous office action.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ried (6,294,331 B1) discloses the use of eosin to autofluoresce

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tissue (col. 1, l. 17-28). Schubert (4,918,000) discloses using fluorescein and rhodamine to fluoresce tissue (col. 1, l. 12-16 and 50 and col. 12, l. 42).

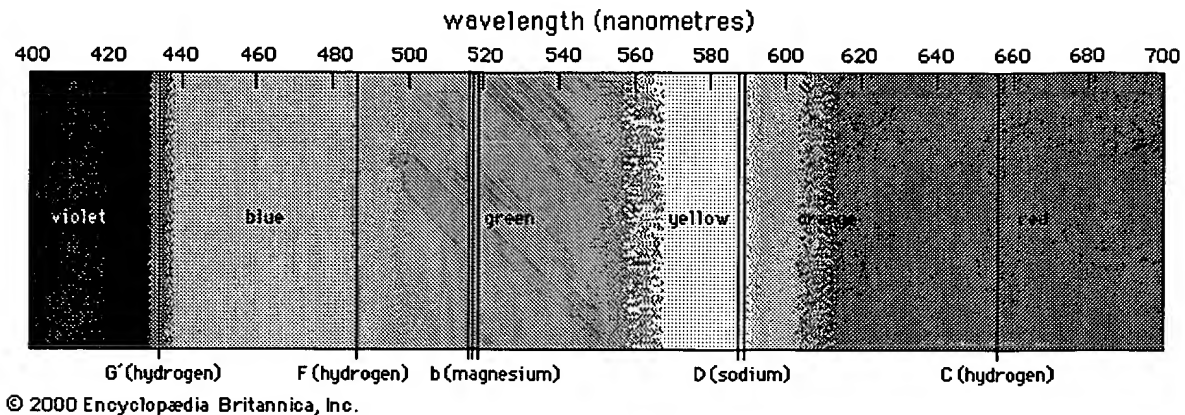
Response to Arguments

10. Applicant's arguments filed 8-29-02 have been fully considered but they are not persuasive. Applicant first argues that the cited references do not disclose, teach or suggests avoiding switching between two different lamps during surgery and thus require the surgeon to adapt his or her eye to different lights of different intensities. Page 15 of Remarks. The Examiner agrees. However in response to this argument, it is noted that the features upon which applicant relies (i.e., not requiring the switching between two different lamps during surgery) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With specific regards to Iacovelli, Applicant argues it would be "impossible to perform a surgery using the fluorescence phenomena of the tissue, since with visible white light, one cannot observe this fluorescence phenomena of the tissue." Page 16 of Remarks. The Examiner disagrees.

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The visible white light spectrum is shown below.



The spectrum shows that white light includes the ultraviolet and blue wavelengths having a spectrum from about 400 to 485 nm. Applicant's specification states that the excitation range of the tissue-specific photosensitizer and tissue autofluorescent occur in the blue (380 to 340 (?) nm) on page 3 and in the range from 370 nm to 500 nm on page 5. Thus, the Examiner disagrees that Iacovelli cannot perform surgery using a white light source to establish a fluorescence phenomena as Applicant contemplated and that one cannot observe the fluorescence phenomena of tissue or tumors in the visible white light spectrum.

Applicant additionally argues that Iacovelli "fails to disclose performing a surgery in the fluorescence modus, i.e. to bring the tissue to fluorescence by irradiating it with a specific excitation light." Page 15 of Remarks. Claims 1 and 23 recite that the marking has a fluorescing substance "*that can be excited to fluoresce* by a light source" and that substance is selected so that its excitation range lies in either a "tumor-specific photosensitizer" (claim 1) or "tissue-autofluorescence" (claim 23). As such, the claims recite a functional limitation *of the marking to fluoresce* and structural limitations of the

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markings in terms of their function to excite when irradiated at certain ranges. There are no limitations in claims 1 and 23 that the device includes an excitation light source outside of the visible light spectrum.

It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. a functional limitation, does not impose any structural limitation upon the claimed apparatus, which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherent capable of performing the function described in a functional limitation, such a functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971).

The combination of Iacovelli and Gain discloses and teaches the functional limitation of the marking has "a fluorescing substance that can be excited to fluoresce by a light source" as recited in claims 1 and 23. As presented in paragraph 10 of Paper No. 5 Iacovelli discloses an endoscope with photoluminescent markings to improve visibility. However, Iacovelli is silent with regards to the type of photoluminescent material used. The Examiner then cited Gain to teach known photoluminescent material, including materials that fluoresce, used as markings on surgical instruments, which also improve visibility and delineate instruments during surgery. These material,

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as Applicant acknowledges on page 16 of his remarks, fluoresces using a white light source.

Furthermore, the Examiner also elaborated on this position above with regards to Gain teaching to use Rhodamine as a photoluminescent material. Rhodamine is a material or fluorescing substance that can be excited to fluoresce by a light source. As evidence for this position, please refer to Richards-Kortum (6,258,576) in column 2, lines 27-59 and column 14, lines 14-45 disclosing the use of Rhodamine as a material that is excited or fluoresce at 442 and 460 nm or within the visible white light spectrum. This discussion also shows that these wavelengths fall in the excitation range of tissue-specific photosensitizers and tissue-autofluorescence of the cervix and tissue examined by a bronchoscope. Thus, the combination of Iacovelli and Gain disclose and teach using a fluorescing marking that can be excited to fluoresce by a light source as recited in claims 1 and 23.

Applicant also argues that Gain does not disclose using a fluorescing substance within the excitation range of either a tumor-specific photosensitizer (claim 1) or a tissue-autofluoresce (claim 23). Page 16 of Remarks. The Examiner disagrees.

Claim 1 recites "wherein the fluorescing substance is selected in such a way that its excitation range lies in an excitation range of a tumor-specific photosensitizer." The Examiner maintains that Gain also teaches a fluorescing substance that is selected such that it is excitable in the range of a tumor-specific photosensitizer. As evidence for this position, the Examiner again refers Applicant to Richards-Kortum and the discussion of Rhodamine. In columns 2 and 14, there is a discussion that Rhodamine

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lies in an excitation range of a tumor-specific photosensitizer with regards to the cervical site (at 460 nm) and those examined by a bronchoscope (at 442 nm). Therefore, the fluorescing substance taught by Gain also has an excitation range of a tumor-specific photosensitizer to discover any diseased tissue, and the Examiner maintains that the combination discloses and teaches all the limitation recited in claim 1.

Claim 23 has a different scope from claim 1 and recites "wherein the fluorescing substance is selected in such a way that its excitation range lies in an excitation range of a tissue-autofluorescence." As evidenced by Richard-Kortum in column 2, lines 27-59 and column 14, lines 14-45, Rhodamine is also a material that can also be excited in the excitation range that lies in an excitation range of a tissue-autofluorescence (at 460 nm) of the cervix. Therefore, the fluorescing substance taught by Gain also has an excitation range of a tissue-autofluorescence, and the Examiner maintains that the combination discloses and teaches all the limitation recited in claim 23.

Applicant argues with respect to Gain that there is no motivation to combine Gain with Iacovelli since Gain was concerned with improving the visibility of an instrument against a tissue background, which is a completely different problem than the present invention. See page 17 of Remarks. The Examiner disagrees with this position. Applicant's specification discusses on page 5 that the fluorescing substance can be used within the range of 400-500 nm, which includes the visible light spectrum. In addition, Applicant is concerned with visibility of the device and tissue in the above-discussed light spectrum by operating to excite the marking to fluoresce within the range of wavelengths discussed. In addition, improving the visibility of the instrument in

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these wavelengths is the precise motivation for combining Gain with Iacovelli. Iacovelli uses photoluminescent material to fluoresce to improve visibility. Gain teaches known photoluminescent materials used in the surgical art to improve visibility. Therefore, Gain does provide a motivation to combine the references to improve visibility during surgery in the same spectrum as Applicant contemplated and is not addressing a completely different problem.

Applicant argues that if Iacovelli and Gain were combined they would reach the invention recited. Page 17 of Remarks. The Examiner disagrees for the above-stated reasons.

Lastly, Applicant argues that the tertiary references do not disclose an instrument with a fluorescing substance selected in excitation range of either a tumor-specific photosensitizer or a tissue-autofluorescence. Page 17 of Remarks. Since the combination of Iacovelli and Gain disclose and teach this feature, there is no requirement that tertiary references also teach these features.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise M. Pothier whose telephone number is 703.308.0993. The examiner can normally be reached on Monday-Thursday and alternate Fridays. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be **directed to the receptionist** of Technology Center 3700, whose telephone number is (703) 308-1148.


Denise Pothier
Primary Examiner
December 2, 2002